

REMARKS / ARGUMENTS

Claims 1-14 and 21-23 are pending in this application. Claims 21-23 are withdrawn from consideration pursuant to 35 USC 121. The Examiner indicate that claims 1-9 are also withdrawn. However, these claims were not included in the restriction requirement and cover the combination of the three elected species. Therefore, Applicant believes that claims 1-9 are properly pending, rather than withdrawn.

The cancellation of claims 15-20 renders moot any rejections of these claims. Accordingly, Applicants request withdrawal of any rejection of claims 15-20.

Claim 4 has been amended to overcome the objection. Applicants agree that the wording requested by the Examiner is less cumbersome and means the same thing. i.e. that 0 and 4 are included.

Claims 1-20 were rejected under 35 USC 112, first paragraph, for failing to meet the written description and enablement requirements with respect to prodrugs and derivatives. Applicants request reconsideration and withdrawal of this rejection for the reasons that follow.

With respect to the stauporine derivatives in claim 3, one of skill in the art would readily understand how to prepare a stauporine derivative based on the chemical structure and present disclosure. Furthermore, the skilled artisan would expect such compounds to possess FLT-3 inhibiting properties based on the present disclosure. Therefore, Applicants were clearly in possession of the invention of claim 3 as of the filing date.

With respect to prodrugs in claim 1, one of skill also knows how to modify a molecule to create a prodrug of a given pharmaceutical compound without undue experimentation. Therefore, claim 1 is fully enabled and described. In addition, not including prodrugs in the claim would permit one of skill to circumvent the claims by making minor modifications to the compounds specified herein.

Applicants request withdrawal of the rejection under 35 USC 112, first paragraph, for the reasons discussed above.

Claims 1-20 were rejected under 35 USC 112, second paragraph. Applicants request reconsideration and withdrawal of this rejection for the reasons that follow.

It is clear from page 1 of the specification that FLT-3 inhibitors are compounds that inhibit FLT-3 kinase. One of skill in the art would have no difficulty understanding FLT-3 kinase or FLT-3 inhibitor. Therefore, this term is definite in accordance with 35 USC 112, second paragraph.

Claim 1 has been amended to specify that the histone deacetylase inhibitor is abbreviated (HDAI). Applicants believe that this amendment overcomes this basis for the rejection.

Applicants request withdrawal of the rejection under 35 USC 112, second paragraph, for the reasons discussed above.

Claims 1-20 were rejected under 35 USC 103(a) over Remiszewski et al in view of Verner et al and Griffin et al. Applicants request reconsideration and withdrawal of this rejection for the reasons that follow.

The present invention relates to combining two classes of drugs that act in the body by different mechanisms. Remiszewski et al and Griffin et al are relied on for disclosing the use of each class of drug separately for treating certain conditions. Verner et al is relied on as disclosing that HDAs are useful for treating AML and that they can be co-administered with other therapeutic agents. However, the cited sections of Verner et al do not even hint that HDAs should be combined with FLT-3 kinase inhibitors.

Although the prior art discloses that HDAs and FLT-3 kinase inhibitors have utility in some of the same conditions and that HDAs may be combined with other therapeutic agents, nothing in the combined disclosure of the references would lead the skilled artisan to expect that any benefit would be achieved by combining the two distinct classes of drug specified by the present claim. Indeed, based on the references, the skilled artisan would have no motivation to combine the treatments and nothing in the references would lead the skilled artisan to expect a

benefit when the treatments are combined, rather than no benefit or an adverse effect.
Therefore, the present claims are not obvious over the combined disclosure of the references.

Applicants request withdrawal of the rejection under 35 USC 103(a) for the reasons discussed above.

Entry of this amendment and reconsideration and allowance of the claims are respectfully requested.

Novartis Pharmaceuticals Corp.
Patents Pharma
One Health Plaza, Building 104
East Hanover, NJ 07936-1080
(862) 778-7824

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "George R. Dohmann", written over a horizontal line.

George R. Dohmann
Attorney for Applicants
Reg. No. 33,593

Date: October 15, 2008